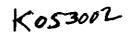
NOV 2 2 2005 SUMMARY OF SAFETY AND EFFECTIVENESS



NAME OF FIRM:

DePuy Orthopaedics, Inc.

P.O. Box 988

700 Orthopaedic Drive Warsaw, IN 46581-0988

510(k) CONTACT:

Natalie S. Heck

Manager, Regulatory Affairs

TRADE NAME:

DePuy CMW 1 Gentamicin Bone Cement

COMMON NAME:

Polymethyl Methacrylate (PMMA) Bone Cement with

Antibiotic.

CLASSIFICATION:

Class II; 21 CFR 888.3027

DEVICE PRODUCT CODE:

MBB

SUBSTANTIALLY EQUIVALENT

DEVICES:

DePuy 1 Gentamicin Bone Cement (K041656)

(now branded DePuy CMW 1 Gentamicin Bone Cement).

SmartSet GMV Endurance Gentamicin Bone Cement

(K033382).

SmartSet MV Endurance Bone cement (P960001/S1)

(previously branded Endurance Bone Cement)

DEVICE DESCRIPTION:

DePuy 1 Gentamicin Bone Cement is a self-curing cement. The cement allows the seating and securing of a metal or plastic prosthesis to living bone. The following modifications are being made:

- DePuy CMW 1 Gentamicin will be made available in a 20 gram presentation in addition to the previously cleared 40 gram presentation.
- Changes are being made to the formulation of the bone cement liquid component.

INTENDED USE AND INDICATIONS:

DePuy CMW 1 Gentamicin Bone Cement is indicated for use in the second stage of a two-stage revision for total joint arthroplasty after the initial infection has been cleared.

BASIS OF SUBSTANTIAL EQUIVALENCE:

Based on similarities in formulations, manufacturing methods and intended use, DePuy believes that DePuy CMW 1 Gentamicin Bone Cement is substantially equivalent to the previously cleared and approved bone cements.



NOV 2 2 2005

Food and Drug Administration 9200 Corporate Boulevard Rockville MD 20850

Natalie Heck Manager, Regulatory Affairs Depuy Orthopaedics, Inc PO Box 988 700 Orthopaedic Drive Warsaw, Indiana 46581-0988

Re: K053002

Trade/Device Name: Depuy CMW 1 Gentamicin Bone Cement

Regulation Number: 21 CFR 888.3027

Regulation Name: Polymethylmethacrylate (PMMA) bone cement

Regulatory Class: II Product Code: MBB Dated: October 24, 2005 Received: October 27, 2005

Dear Ms. Heck:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the <u>Federal Register</u>.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson

Acting Director

Division of General, Restorative and Neurological Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

Indications Statement

| 510(k) Number (if k | nown): | | |
|------------------------------------|-------------------|--|--|
| Device Name: <u>DePu</u> | y CMW 1 Gentamic | in Bone Cement | |
| Indications for Use: | | | |
| | | ent is indicated for us the initial infection l | e in the second stage of a two-stage has been cleared. |
| | · / | | |
| Prescription Use(Part 21 CFR 801.S | ubpart D) | OR/AND | Over-The Counter Use (21 CFR 807 Subpart C) |
| (PLEASE DO NOT NEEDED) | WRITE BELOW 1 | THIS LINE-CONTIN | IUE ON ANOTHER PAGE IF |
| | Concurrence of CD | RH, Office of Devic | e Evaluation (ODE) |
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| | (Division Sign | -000 | Page 1 of |
| | | neral, Restorati | Te, |
| | 510(k) Numbe | K053002 | . |